

§ 878.3900

premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §878.9. If the device is intended for use without an external prosthesis adhesive to fasten it to the body, the device is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.

[53 FR 23872, June 24, 1988, as amended at 59 FR 63010, Dec. 7, 1994; 66 FR 38802, July 25, 2001]

§ 878.3900 Inflatable extremity splint.

(a) *Identification.* An inflatable extremity splint is a device intended to be inflated to immobilize a limb or an extremity.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §878.9.

[53 FR 23872, June 24, 1988, as amended at 59 FR 63010, Dec. 7, 1994; 66 FR 38802, July 25, 2001]

§ 878.3910 Noninflatable extremity splint.

(a) *Identification.* A noninflatable extremity splint is a device intended to immobilize a limb or an extremity. It is not inflatable.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §878.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of §820.180 of this chapter, with respect to general requirements concerning records, and §820.198 of this chapter, with respect to complaint files.

[53 FR 23872, June 24, 1988, as amended at 54 FR 13827, Apr. 5, 1989; 65 FR 2317, Jan. 14, 2000]

§ 878.3925 Plastic surgery kit and accessories.

(a) *Identification.* A plastic surgery kit and accessories is a device intended

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to be used to reconstruct maxillofacial deficiencies. The kit contains surgical instruments and materials used to make maxillofacial impressions before molding an external prosthesis.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §878.9.

[53 FR 23872, June 24, 1988, as amended at 54 FR 13827, Apr. 5, 1989; 65 FR 2317, Jan. 14, 2000]

Subpart E—Surgical Devices

§ 878.4014 Nonresorbable gauze/sponge for external use.

(a) *Identification.* A nonresorbable gauze/sponge for external use is a sterile or nonsterile device intended for medical purposes, such as to be placed directly on a patient's wound to absorb exudate. It consists of a strip, piece, or pad made from open woven or nonwoven mesh cotton cellulose or a simple chemical derivative of cellulose. This classification does not include a nonresorbable gauze/sponge for external use that contains added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in part 807, subpart E of this chapter subject to the limitations in §878.9.

[64 FR 53929, Oct. 5, 1999]

§ 878.4018 Hydrophilic wound dressing.

(a) *Identification.* A hydrophilic wound dressing is a sterile or non-sterile device intended to cover a wound and to absorb exudate. It consists of nonresorbable materials with hydrophilic properties that are capable of absorbing exudate (e.g., cotton, cotton derivatives, alginates, dextran, and rayon). This classification does not include a hydrophilic wound dressing that contains added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in part 807, subpart E of this chapter subject to the limitations in § 878.9.

[64 FR 53929, Oct. 5, 1999]

§ 878.4020 Occlusive wound dressing.

(a) *Identification*. An occlusive wound dressing is a nonresorbable, sterile or non-sterile device intended to cover a wound, to provide or support a moist wound environment, and to allow the exchange of gases such as oxygen and water vapor through the device. It consists of a piece of synthetic polymeric material, such as polyurethane, with or without an adhesive backing. This classification does not include an occlusive wound dressing that contains added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in part 807, subpart E of this chapter subject to the limitations in § 878.9.

[64 FR 53929, Oct. 5, 1999]

§ 878.4022 Hydrogel wound dressing and burn dressing.

(a) *Identification*. A hydrogel wound dressing is a sterile or non-sterile device intended to cover a wound, to absorb wound exudate, to control bleeding or fluid loss, and to protect against abrasion, friction, desiccation, and contamination. It consists of a nonresorbable matrix made of hydrophilic polymers or other material in combination with water (at least 50 percent) and capable of absorbing exudate. This classification does not include a hydrogel wound dressing that contains added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in part 807, subpart E of this chapter subject to the limitations in § 878.9.

[64 FR 53929, Oct. 5, 1999]

§ 878.4025 Silicone sheeting.

(a) *Identification*. Silicone sheeting is intended for use in the management of closed hyperproliferative (hypertrophic and keloid) scars.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 878.9.

[69 FR 48148, Aug. 9, 2004]

§ 878.4040 Surgical apparel.

(a) *Identification*. Surgical apparel are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Examples include surgical caps, hoods, masks, gowns, operating room shoes and shoe covers, and isolation masks and gowns. Surgical suits and dresses, commonly known as scrub suits, are excluded.

(b) *Classification*. (1) Class II (special controls) for surgical gowns and surgical masks.

(2) Class I (general controls) for surgical apparel other than surgical gowns and surgical masks. The class I device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9.

[53 FR 23872, June 24, 1988, as amended at 65 FR 2317, Jan. 14, 2000]

§ 878.4100 Organ bag.

(a) *Identification*. An organ bag is a device that is a flexible plastic bag intended to be used as a temporary receptacle for an organ during surgical procedures to prevent moisture loss.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9.

[53 FR 23872, June 24, 1988, as amended at 59 FR 63010, Dec. 7, 1994; 65 FR 2318, Jan. 14, 2000]

§ 878.4160 Surgical camera and accessories.

(a) *Identification*. A surgical camera and accessories is a device intended to be used to record operative procedures.